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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,068	08/27/2003	Joseph L. Mark	65937-0037	4645

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EXAMINER	
SOLANKI, PARIKHA	
ART UNIT	**PAPER NUMBER**
3737	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/649,068	MARK ET AL.	
	Examiner	Art Unit	
	Parikha Solanki	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-11,13-17,19-21,23-34,36-42 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-11,13-17,19-21,23-34,36-42 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/17/06*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 20 February 2007 have been fully considered but they are not persuasive. Applicant argues that the stylet of Werne (US Patent No. 5,782,754) is neither removably disposed within the catheter, nor does it substantially extend beyond the distal tip of the catheter.

Examiner acknowledges that Werne ('754) does teach that, during delivery of the cannula to the anatomic region of interest, the stylet position is fixed in order to reliably and consistently visualize the tip of the catheter during navigation to the tumor. However, Werne ('754) does not teach that the stylet is permanently fixed within the catheter. In contrast, Werne ('754) provides ample teaching and support for the stylet to be removably and slidably disposed within the catheter as claimed in the instant application. Examiner respectfully directs Applicant's attention to col. 9 lines 57-58 of Werne ('754), which explicitly reads "a marker stylet 42 is removably positioned within the central chamber of the body 40". Furthermore, in col. 7 lines 9-12, Werne ('754) expressly recites "a marker stylet ... fits removably inside a central channel of the device".

Regarding the length of the stylet, Examiner respectfully directs Applicant's attention to Figure 8 of Werne ('754), which clearly shows the tip of the stylet extending beyond the tip of the catheter. The term "substantially," as recited in the claims of the instant application, is a relative term which is not supported by further explicit numeric definition in Applicant's written disclosure nor in the instant claims. Therefore, one of reasonable skill in the art would expect Applicant's invention to perform equally well with a stylet of any length, so long as its distal tip extends beyond that of the cannula.

In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Regarding Applicant's additional arguments that Werne ('754) does not fully anticipate the instant invention set forth by the currently amended claims, these arguments have been fully considered and are persuasive. Therefore, the previous rejection has been withdrawn in view of Applicant's

amendments. However, upon further consideration, a new ground(s) of rejection is made in view of Balbeirz (US Patent No. 6,869,430) and Hurtak (WO 98/55016).

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 17 November 2006 was filed after the mailing date of the first Office Action on 18 October 2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 6, 13-17, 20, 25 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Balbierz (US Patent No. 6,869,430), hereinafter Balbierz ('430).

Regarding claims 1, 2 and 6, Balbierz ('430) discloses a tissue biopsy device including a cannula having open proximal and distal ends and an introducer for a plurality of resilient members of length longer than that of the cannula, wherein the members are removably disposed and selectively insertable within the cannula (Fig. 1, col. 5 lines 40-44, col. 16 lines 11-16). The resilient members of Balbierz ('430) constitute a stylet and a target confirmation device as claimed in the instant application. The distal ends of both the stylet and target confirmation device of Balbierz ('430) extend substantially beyond the distal end of the cannula (Fig. 1). Balbierz ('430) discloses that the cannula is configured to introduce a biopsy device (col. 5 lines 26-60). Balbierz ('430) discloses the system for use with MRI, thereby making it MRI compatible as claimed in the instant application (col. 25 line 2).

Regarding claim 13, Balbierz ('430) additionally states that the introducer can be configured to pierce tissue (col. 5 lines 55-56).

Regarding claims 14, 15 and 17, the system of Balbierz ('430) also includes a fluid conduit for delivering fluid provided in communication with the lumen, a one-way valve and a two-way valve (col. 17 lines 37-44). The one-way valve and two-way valve of Balbierz ('430) constitute a hemostatic valve and a directional valve, respectively, as claimed in the instant application.

Regarding claim 16, Balbierz ('430) shows that the proximal end of the target confirmation device 24 engages the proximal end of the outer cannula (Fig. 2), and further states that the proximal end of the device may comprise a port or actuator (col. 6 lines 1-2), any of which would constitute the fitting interfaces claimed in the instant application.

Regarding claims 20 and 33, Balbierz ('430) provides a handpiece and a rotatable tissue-receiving opening for removing tissue from the target site (col. 17 lines 57-63).

Regarding claim 25, Balbierz ('430) shows that each of the resilient members are approximately equal in length (Fig. 1).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 4, 5, 8-11, 19, 26, 28, 34, 42 and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz ('430) in view of Hurtak (WO 98/55016), hereinafter Hurtak ('016), previously cited by Examiner in a prior Office Action.

Regarding claims 4, 5, 7-11, 19 and 36-39, Balbierz ('430) substantially teaches all features of the present invention as previously applied to claims 1, 2, 6, 13-17 and 20. Balbierz ('430) does not teach a target confirmation device with an MRI-visible marking band at the distal end. In the same problem solving area, Hurtak ('016) teaches an MRI-compatible guidewire, equivalent to a target confirmation device, with an MRI-visible contrast band at the distal tip (p. 3 lines 14-23, Fig. 1). Hurtak ('016) teaches that the contrast band is of relatively low artifact generating material (p. 5 lines 18-21). Hurtak ('016) also provides motivation for an MRI-compatible guidewire that can be visualized without introducing significant artifact into the acquired patient image data (p. 3 lines 6-13). Furthermore, it is well known in the art that, during minimally invasive interventional procedures, both a stylet and guidewire may be sequentially disposed within a catheter or cannula in order to reach a target site within the body; the stylet

is generally used first to augment catheter stability for facilitating coarse navigation to the target site, and then the stylet is removed and replaced by a guidewire for more precise navigation within the target site. It would have been obvious to one of ordinary skill in the art at the time of invention to use the wire of Hurtak ('016) with the biopsy system of Balbierz ('430), in view of the teachings of Hurtak ('016).

Regarding claim 28, by teaching that the guidewire is MRI-visible, Hurtak ('016) implicitly teaches the step of imaging the guidewire.

Regarding claims 34 and 42, Balbierz ('430) provides a rotatable tissue-receiving opening for removing tissue from the target site (col. 17 lines 57-63).

7. Claims 21, 23, 24, 27, 29-32, 41 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz ('430) in view of Hurtak ('016), further in view of Werne (5,782,764).

Regarding claims 21, 23, 24 and 40, Balbierz ('430) and Hurtak ('016) substantially teach all features of the present invention as previously discussed. Balbierz ('430) and Hurtak ('016) fail to discuss the length of the target confirmation device relative to the position of a tissue receiving opening of the cutting element. In the same field of endeavor, Werne ('764) teaches a cutting element with a guidewire disposed therein (Figs. 8-10). Werne ('764) shows that the distance between the proximal and distal ends of the guidewire is approximately equal to the distance between the center of the tissue receiving opening and handpiece of the biopsy device. It would have been obvious to one of ordinary skill in the art at the time of invention to use the biopsy device/stylet arrangement of Werne ('764) with the wire of Hurtak ('016), inside the system of Balbierz ('430) in order to better visualize the end of the biopsy device in an MRI image as taught by Werne ('764).

Regarding claims 27, 29-32, 41 and 50, Werne ('764) teaches the step of imaging the target tissue prior to or contemporaneous with insertion of the stylet (Abstract). Werne ('764) additionally teaches insertion of a biopsy device within an outer cannula in order to obtain a tissue sample for further testing (Figs. 9 & 10). Although Werne ('764) does not expressly discuss aspiration of the biopsy site after resection, this step is commonly known and performed in state of the art biopsy procedures, and Balbierz ('430) additionally provides aspiration means within the system (col. 17 lines 57-58). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the system and method of Balbierz ('430), previously modified by Hurtak ('016), to include the means and steps of Werne ('764) in order to obtain a biopsy sample of the target tissue, in view of the teachings of Werne ('764).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lurie et al (US Patent No. 6,277,107) disclose a related introducer/stylet/guidewire system with a hemostatic valve for implanting cardiac pacemaker or defibrillator leads, which is considered the same problem-solving area as that of the instant application.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha Solanki whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Parikha Solanki
Examiner – Art Unit 3737

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